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Filing Date	March 10, 2000
First Named Inventor	WILLIAMS, LEWIS T.
Group Art Unit	1631
Examiner Name	BRUSCA, JOHN S.
Total Number of Pages in This Submission: 8	Attorney Docket Number: 2300-1481

ENCLOSURES (check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
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  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
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- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Documents
- ☐ Response to Missing Parts/ Incomplete Application
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- ☐ Assignment Papers *(for an Application)*
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- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☒ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below):*

1. Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Signing Attorney/Agent (Reg. No.)	JAMES S. KEDDIE, PH.D., 48,920 BOZICEVIC, FIELD & FRANCIS LLP
Signature	James S Keddie
Date	June 4, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	)	
	)	Group Art Unit: 1631
Williams *et al.*	)	
	)	Examiner: John S. Brusca
Serial No. 09/297,648	)	
	)	Atty. Docket No. 2300-1481
Filed: March 10, 2000	)	PP-1481-002

For: **HUMAN GENES AND GENE EXPRESSION PRODUCTS II**

REPLY BRIEF

Commissioner of Patents
Alexandria, V.A. 20231

Sir:

This Reply Brief is in response to the Examiner's Answer mailed by the Office on April 6, 2004.

Please any required fees to our Deposit Account No. 50-0815, order number 2300-1481.

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TABLE OF AUTHORITIES

Cases

REPLY BRIEF

In this Reply Brief, the Appellants address three assertions made by the Office in the Examiner's Answer (EA). Appellants note that all arguments presented in the prior communications apply with equal force, but are not reiterated here solely in the interest of brevity and for the convenience of the Board.

First, the Examiner's Answer attempts to dismiss the declaration of Dr. Somerville because it "fails to provide any evidence that the specification describes the sequences of the claimed full length cDNA, genomic sequences, or undisclosed fragments thereof that are claimed." Examiner's Answer ("EA") page 5, final paragraph.

The Office is, therefore, attempting to dismiss Dr. Somerville's declaration because it assertedly fails to provide any evidence that the specification describes two specific sequences -- full length cDNA and genomic sequences -- that are encompassed by the appealed claims.

In response, and as discussed in great length in the Appeal Brief (see Appeal Brief ("AB") page 9 line 13 to page 10, line 13; AB page 16, line 19 to page 17 line 8; page 31, line 10 to page 35, line 18), none of the appealed claims require that the claimed polynucleotides are full length cDNA or have any particular structure or biological function. The cDNA and genomic sequences referred to by the Office are but two species encompassed by the appealed claims.

As previously argued, the fact that Appellants' generic claims encompass a species which is not explicitly described in the specification is irrelevant as to whether Appellants are entitled to the appealed claims. see AB page 9 line 13 to page 10, line 13; page 16, line 19 to page 17 line 8; page 31, line 10 to page 35, line 18. There is no requirement that every species of a claimed

genus be specifically described in a patent specification in order to satisfy 35 U.S.C. §112, ¶1. In particular, there is no law that requires disclosure of a full length cDNA or genomic sequence in order for claims such as those appealed herein to meet the written description standard of 35 U.S.C. §112, ¶1.

Accordingly, Dr. Somerville's declaration should not be dismissed simply because it fails to provide any evidence that the specification describes two particular species encompassed by the appealed claims. This is an improper application of the law.

Furthermore, Appellants again note that Dr. Somerville's declaration is, in and of itself, evidence that the written description requirement of 35 U.S.C. §112, ¶1 is satisfied.

Secondly, the Examiner's Answer argues that the Appellants fails to show how "an increased skill level would allow one of skill in the art to understand that the Appellants had, at the time of filing, possession of a claimed species such as full length cDNA corresponding to SEQ ID NO:253." EA page 6, middle paragraph.

Again, the Office inappropriately focuses on a single species that is encompassed by the claims (i.e., full length cDNA corresponding to SEQ ID NO:253) and asserts that the Appellants have provided no evidence supporting possession of that particular species at the time of filing.

As discussed above and as previously argued in great detail in the Appeal Brief, the fact that Appellants' generic claims encompass a species which is not explicitly described in the specification is irrelevant as to whether Appellants are entitled to the appealed claims. see AB page 9 line 13 to page 10, line 13; AB page 16, line 19 to page 17 line 8; page 31, line 10 to page 35, line 18. There is no requirement that every species of a claimed genus be specifically described in a patent specification in order to satisfy 35 U.S.C. §112, ¶1. In particular, there is no

law that requires disclosure of a full length cDNA or genomic sequence in order for claims such as those appealed herein to meet the written description standard of 35 U.S.C. §112, ¶1.

Accordingly, the Office's arguments represent an improper application of the law and, as such, carry no weight.

As discussed in greater detail on pages of the Appeal Brief, a patent application is to be viewed from the standpoint of one of ordinary skill in the art in the relevant field at the time of filing of the application *See, e.g., Ralston Purina Co. v. Far-Mar-Co,* 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985), *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). *See also All Dental Prodx, LLC v. Advantage Dental Products, Inc.*, 2002 U.S. App. LEXIS 22372, *10-11 (Fed. Cir. 2002). Accordingly, the requirements for meeting the written description standard of 35 U.S.C. § 112, first paragraph depend on the level of skill possessed by one of ordinary in the art. For inventions in rapidly evolving fields, the standards for written description may therefore change.

The particular field of the present invention (recombinant DNA technology) is rapidly evolving. This is not disputed.

However, the cases cited by the Office in support of the written description rejection (i.e., *University of California v. Eli Lilly and Co, Fiers v. Sugano*, 984 F.2d 1164, 25 U.S.P.Q.2d (BNA) 1601 (Fed. Cir. 1993), *Amgen Inc. v. Chugai Pharmaceutical Co.* , 927 F.2d 1200, 18 U.S.P.Q.2d (BNA) 1016 (Fed. Cir. 1991), *Fiddes v. Baird* 30 U.S.P.Q.2d 1481 (Bd. of Appeals 1993)) relate to patent applications that were filed between the late 1970s and the mid-1980s.

As previously argued and as declared by Dr. Somerville, a Skilled Person had a dramatically higher level of skill in March 2000 (the filing date of the instant application) as

compared to the filing dates in the above-referenced cases. In fact, Dr. Somerville does not believe that a statement regarding what one of ordinary skill can or cannot do at the time of filing of the applications at issue in the above cases could be used as evidence with respect to what the Skilled Person in March of 2000 could or could not do. SD ¶ 47

Accordingly, the Appellants re-iterate their arguments that the above-referenced cases are not applicable to the instant case at least because the decisions of these cases turn on what one of skill in the art could or could not do at the time of filing approximately 20 years ago, which, as we have established, is dramatically different to what one of skill in the art could or could not do in March 2000.

Finally, the Examiner's Answer argues that the commercial value of a patent is irrelevant to the question of whether the claims are valid. EA page 7, first paragraph. However, this is not what is being argued by the Applicants.

What is being argued is that the Office does not achieve the constitutional purpose of the U.S. patent system when it attempts to force patentees to accept claims of literally no value when there is no legal or factual basis for such action. The U.S. patent system was not designed to provide meaningless protection. Instead, the U.S. patent system is designed to "promote the progress of science and the useful arts." U.S. Constitution, Art. 1, 8. To unduly limit the scope of the claims so as to render the claims impotent in the market place does not, indeed, promote the progress of science and the useful arts.

As the Court of Customs and Patent Appeals has stated:

> The public purpose on which the patent law rests requires the granting of claims commensurate in scope with the invention disclosed. This requires as much the granting of broad claims on broad inventions as it does the

> granting of more specific claims on more specific inventions. It is neither contemplated by the public purpose of the patent laws nor required by the statute that an inventor shall be forced to accept claims narrower than his invention in order to secure allowance of his patent. It is, however, consistent with this public purpose embodied in the pertinent statutory requirement that the *invention claimed* shall be no broader than the *invention set forth* in the written description forming part of the specification.

In re Sus and Schaefer, 306 F.2d 494, 497, 134 U.S.P.Q. (BNA) 301, 304 (C.C.P.A., 1962), emphasis in original.

The invention set forth in the instant application is a polynucleotide comprising 50 contiguous nucleotides of SEQ ID NO:253. Such a polynucleotide is being claimed.

CONCLUSION

For the reasons given above, the rejection of claims 146-154 under 35 U.S.C. § 112, ¶1 is improper. The Board of Patent Appeals and Interferences should reverse the rejection.

Respectfully submitted,
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